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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/723,199	Applicant(s) FRUHLING ET AL.	
	Examiner Paul Kim	Art Unit 2161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 17, 18, 20-22, 24, 27-31, 34, 35, 37, 39-41, 46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 17, 18, 20-22, 24, 27-31, 34, 35, 37, 39-41 and 46-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to the following communication: Amendment filed on 8 March 2007.
2. Claims 17-18, 20-22, 24, 27-31, 34-35, 37, 39-41, and 46-47 are pending and present for examination.

Response to Amendment

3. Claims 1-16, 23, 25-26, 32-33, 36, 38, 42-45 have been cancelled.
4. Claims 17-18, 22, 27-28, 30-31, 35, 37, and 39-40 have been amended.
5. Claims 46-47 have been added.

Drawings

6. The drawings were received on 8 March 2007. These drawings are acceptable.
7. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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9. **Claims 17-18, 20-22, 24, 27, 30-31, 34,-35, 37, 39, and 46-47** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed toward a method and system "for managing specimen data reporting among specimen collection facilities" and are non-statutory because they do not encompass tangible subject matter and/or embodiments which fall within a statutory category.

The claims fail to recite a "useful, concrete and tangible result" since claims 17 and 30 merely recite the selection of multiple specimen collection facilities with the intended use of "send[ing] the specimen report in accordance with said determined correlation." Therefore, since an intended use is not afforded patentable weight and the claims fail to recite the method step of sending the specimen report, the claims fail to recite a "useful, concrete and tangible result." See *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601-02. MPEP 2106. "The claimed invention as a whole must accomplish a practical application. That is, it must produce a 'useful, concrete and tangible result' " (emphasis added).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. **Claims 17, 30, and 46-47** are rejected under 35 U.S.C. 102(e) as being anticipated by Jamroga et al (U.S. Patent No. 6,574,742), hereinafter referred to as JAMROGA, filed on 10 November 2000, and issued on 3 June 2003.

12. **As per independent claims 17 and 30**, JAMROGA teaches:

A method for managing specimen data reporting among specimen collection facilities, said method comprising:

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receiving a specimen report from a client terminal {See JAMROGA, C7:L11-14, wherein this reads over "[b]y 'participant institution' is meant hospitals, radiology group practices, physician group practices, medical image centers, and other healthcare facilities and organizations"}, wherein the specimen report comprises a specimen description including specimen image data {See JAMROGA, C9:L23-34, wherein this reads over "[e]ach set of delivery instructions and accompanying data on database is stored and retrievable under a unique identifier or identifiers. The identifiers comprise an identification of the particular instruction set for the names participant institution"};

processing the specimen report in accordance with a facility identifier corresponding to the specimen collection facility at which the client terminal is located {See JAMROGA, C9:L48-59, wherein this reads over "the proxy server upon acceptance of delivery instructions automatically calculates the particular instruction sets as initial data received. Upon calculation that the requested transaction is a storage request the proxy server calculates and associates a digital signature with the received data or image"}, said processing including storing the specimen description in association with the facility identifier in a network accessible data storage device {See JAMROGA, C10:L43-52, wherein this reads over "the central database can be comprised of one or more databases located remotely from each other"};

storing specimen handling data that specifies specimen handling capabilities of multiples specimen collection facilities {See JAMROGA, C11:L42-53, wherein this reads over "[t]he proxy server 32 layer preferably interfaces with DICOM compliant medical radiology modalities 62 located on the participant's network 34, for the purpose of either manually or automatically providing a communication and storage device for transmitting and storing various DICOM or non-DICOM compliant data and images generated from such modalities"};

determining a correlation between the specimen image data and specimen handling capability data {See JAMROGA, C11:L42-54, wherein this reads over "various DICOM or non-DICOM compliant data and images"; and C11:L65-C12:L10}; and

selecting one or more of the multiple specimen collection facilities to send the specimen report in accordance with said determined correlation {See JAMROGA, C11:L48-53, wherein this reads over "[t]he proxy server 32 layer includes and encompasses all necessary DICOM specific communication protocols . . . "};

13. As per dependent claims 46 and 47, JAMROGA teaches:

The method of claim 17, wherein said determining a correlation is performed using a rule-based algorithm, an inference engine, or a neural network {See JAMROGA, Figure 1}.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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15. **Claims 18-21 and 31-34** are rejected under 35 U.S.C. 103(a) as being unpatentable over JAMROGA, in view of Kaltanji (USPGPUB 2004/0165791, hereinafter referred to as KALTANJI), filed on 21 February 2003, and published on 26 August 2004.

JAMROGA teaches all the limitations of claims 17 and 30 for the reasons stated above.

JAMROGA differs from the claimed invention in that JAMROGA fails to specifically disclose the use of file directories having directory names corresponding to a facility identifier (claims 18 and 31).

JAMROGA differs from the claimed invention in that JAMROGA fails to specifically disclose the representation of file directories as graphical user interface folders (claims 19 and 32).

JAMROGA differs from the claimed invention in that JAMROGA fails to specifically disclose the storage of specimen descriptors in association with the facility identifiers (claims 20 and 33).

JAMROGA differs from the claimed invention in that JAMROGA fails to specifically disclose the copying of digital images files into a digital image library directory (claims 21 and 34).

16. **As per dependent claims 18 and 31**, JAMROGA, in combination with KALTANJI, discloses:

The method of claim 17, wherein said storing the specimen description in association with the facility identifier comprises copying the specimen description into one or more file directories having directory names corresponding to the facility identifier {See KALTANJI, [0033], wherein this reads over "the directory name format of each sub-directory will include a unique patient identifier for that particular patient, which can include any number of indicia"}.

KALTANJI discloses a method wherein the directory name format may include any number of indicia which reflect a certain attribute or property of the data stored therein. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by KALTANJI.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA could have file directories which stored specimen description data according to the facility identifiers.

17. **As per dependent claims 19 and 32**, JAMROGA, in combination with KALTANJI, discloses:

The method of claim 18, wherein the one or more file directories are represented as graphical user interface folders {See KALTANJI, Figure 2}.

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KALTANJI discloses a method wherein a graphical user interface, which displays certain folders, is used. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by KALTANJI.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would allow for a user to easily access the folders in the system.

18. **As per dependent claims 20 and 33**, JAMROGA, in combination with KALTANJI, discloses:

The method of claim 17, wherein said storing the specimen description in association with the facility identifier comprises associating the specimen description with the facility identifier in one or more database records {See KALTANJI, [0036], wherein this reads over "[t]he file name format of each dental image file will typically include a number of indicia such as a patient identifier, a file creation date, a file creation time, a modification date, a description of the source from which the image was derived, and an image description"}.

KALTANJI discloses a method wherein the file name format of the images may include "a description of the source from which the image was derived." Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by KALTANJI.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would comprise of the database records which identified the source facility identifier by associating the specimen description with a facility identifier.

19. **As per dependent claims 21 and 34**, JAMROGA, in combination with KALTANJI, discloses:

The method of claim 18, wherein the specimen image data is contained in one or more digital image files, said copying the specimen description into one or more file directories further comprising copying the one or more digital image files into a digital image library directory, the digital image library directory having a directory name corresponding to the facility identifier {See JAMROGA, C10:L43-52, wherein this reads over "the central database can be comprised of one or more databases located remotely from each other, each acting as a redundant back-up database for the other for purposes of storing data and images for retrieval in case of disaster or destruction of the other database"}.

KALTJANI discloses a method for have more than one database for the purposes of "a redundant back-up database." Therefore, it would have been obvious to one of ordinary skill in the art at the time

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the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by KALTANJI.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would further comprise of a digital image library directory wherein digital images are copied into.

20. **Claims 23, 29 and 41** are rejected under 35 U.S.C. 103(a) as being unpatentable over JAMROGA, in view of IMAI, and in further view of Payne et al (U.S. Patent No. 6,021,433, hereinafter referred to as PAYNE), filed on 24 January 1997, and issued on 1 February 2000.

JAMROGA teaches all the limitations of claims 17 and 30 for the reasons stated above.

JAMROGA differs from the claimed invention in that JAMROGA fails to specifically disclose the use of audio alert signals and alert messages (claims 23, 29 and 41).

21. **Claim 22, 24, 35, and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over JAMROGA, in view of Imai et al (U.S. Patent No. 5,987,510, hereinafter referred to as IMAI), filed on 8 November 1996, and issued on 16 November 1999.

JAMROGA teaches all the limitations of claims 17 and 30 for the reasons stated above.

JAMROGA differs from the claimed invention in that JAMROGA fails to specifically disclose the processing of specimen reports in order of their priority levels (claims 22, 24, 35, and 37).

22. **As per dependent claims 22 and 35**, JAMROGA, in combination with IMAI, discloses:

The method of claim 17, wherein the received specimen report further includes a priority level indicator {See IMAI, C10:L36-37, wherein this reads over "the individual data of each file can include a file size, a priority level, etc."} selected from among priority level indicia representing levels of urgency associated with the specimen report, said method further comprising processing the received specimen report in accordance with the priority level indicator {See IMAI, C10:L52-55, wherein this reads over "the processing is sequentially carried out for the sorted files in the priority level order"}, said processing the received specimen report in accordance with the priority level indicator comprising triggering a user alert signal in accordance with the level of urgency represented by the priority level indicator included with the specimen report {See PAYNE, C30:L9-13, wherein this reads over "[w]hen the alert message is received . . . an animated visual and/or audio notification is triggered"}.

IMAI discloses a method wherein the files can also include a priority level and processed accordingly. Therefore, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by IMAI.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would allow for specimen reports to be processed in order of their priority levels.

23. **As per dependent claim 24**, JAMROGA, in combination with IMAI, discloses:

The method of claim 22, wherein said processing the received specimen report in accordance with the priority level indicator comprises storing the specimen report in association with the priority level indicator in a network accessible data storage device {See IMAI, C10:L36-37, wherein this reads over "the individual data of each file can include a file size, a priority level, etc."}.

IMAI discloses a method wherein the files can also include a priority level and processed accordingly. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by IMAI.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would allow for specimen reports to be processed in order of their priority levels.

24. **As per dependent claim 37**, JAMROGA, in combination with IMAI, discloses:

The method of claim 24, wherein said storing the specimen report in association with the priority level indicator comprises associating the priority level indicator with the specimen report {See IMAI, C10:L36-37, wherein this reads over "the individual data of each file can include a file size, a priority level, etc."} in one or more database records.

IMAI discloses a method wherein the files can also include a priority level and processed accordingly. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the invention disclosed by IMAI.

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One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would allow for specimen reports to be processed in order of their priority levels.

25. **Claims 27 and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over JAMROGA, in view of IMAI, and in further view of Ecker et al (USPGPUB 2003/0082539, hereinafter referred to as ECKER), filed on 26 June 2001, and published on 1 May 2003.

JAMROGA teaches all the limitations of claims 17 and 30 for the reasons stated above.

JAMROGA differs from the claimed invention in that JAMROGA fails to specifically disclose the determination and assignment of epidemiological threat levels for specimens (claims 27 and 39).

26. **As per dependent claims 27 and 39**, JAMROGA, in combination with IMAI and ECKER, discloses:

The method of claim 17, further comprising:

determining an epidemiological threat level in accordance with the specimen description {See ECKER, [0087], wherein this reads over "[c]omparison of newly observed bioagents to known bioagents is also possible, for examination of threat level, by comparing their BCS to those of known organisms"}; and

assigning a priority level designation to the received specimen report in accordance with the determined epidemiological threat level {See IMAI, C10:L36-37, wherein this reads over "the individual data of each file can include a file size, a priority level, etc."}.

ECKER discloses a method wherein epidemiological threat levels may be assigned in accordance with the specimen description by comparing the specimens to other known bioagents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the inventions disclosed by IMAI and ECKER.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would further comprise of assigning certain priority levels to specimens in accordance with the epidemiological threat level so that such specimens may be processed according to their threat levels.

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27. **Claims 28-29 and 40-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over JAMROGA, in view of IMAI and ECKER, and in further view of PAYNE

JAMROGA teaches all the limitations of claims 17 and 30 for the reasons stated above.

JAMROGA differs from the claimed invention in that JAMROGA fails to specifically disclose the determination and assignment of epidemiological threat levels for specimens (claims 28-29 and 40-41).

28. **As per dependent claims 28 and 40**, JAMROGA, in combination with IMAI, ECKER, and PAYNE, discloses:

The method of claim 27, further comprising delivering an alert message to at least one other specimen collection facility, wherein the alert message includes the specimen description associated with the facility identifier and the priority level designation {See PAYNE, C30:L17-24, wherein this reads over "the alert is not limited to the provider ID code number and name. Rather, the E-mail alert could include a header, whole message, etc"}.

PAYNE discloses a method wherein an alert message is sent include a variety of related information. It would have been obvious to one of ordinary skill in the art to have the alert message include a description of the specimen and the priority level. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above invention suggested by JAMROGA by combining it with the inventions disclosed by IMAI, ECKER and PAYNE.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would further disclose to a user the priority level and a description of the specimen in an alert message.

29. **As per dependent claims 29 and 41**, JAMROGA, in combination with IMAI, ECKER, and PAYNE, discloses:

The method of claim 28, further comprising, responsive to said delivering an alert message to at least one other specimen collection facility, storing an alert message status record {See PAYNE, C30:L17-24, wherein this reads over "the date and time the alert was received"}.

PAYNE discloses a method wherein an alert message may be delivered to another specimen collection facility, and an alert message status record is stored (i.e. the date and time the alert was received may be stored). Therefore, it would have been obvious to one of ordinary skill in the art at the

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time the invention was made to modify the above invention suggested by JAMROGA by combining it with the inventions disclosed by IMAI and PAYNE.

One of ordinary skill in the art would have been motivated to make such a modification so that the invention disclosed in JAMROGA would further comprise of delivering an alert message to other specimen collection facilities and storing an alert message status record.

Response to Arguments

30. Applicant's arguments filed 8 March 2007 have been fully considered but they are not persuasive.

a. Rejections under 35 U.S.C. 102

Applicant asserts the argument that "nothing in Jamroga, Imai, and Payne, individually or in any combination, disclose or suggest a feature whereby a database manager correlates specimen report content, and particularly image data content, with the specimen handling capabilities of specimen handling facilities to use this correlation to determine which facilities will receive the report" {See Amendment, page 9}. The Examiner respectfully disagrees in that Jamroga discloses a system wherein DICOM and non-DICOM compliant data and images are differentiated as are those storage and retrieval warehouses designed for DICOM images. Furthermore, wherein Jamroga discloses the use of a proxy server layer which "includes and encompasses all necessary DICOM specific communication protocols" it would have been obvious to one of ordinary skill in the art that said disclosure would read upon the amended language recited in claims 17 and 30.

Additionally, it is noted that the claims as recited propose an intended use for the selection of the multiple specimen collection facilities. Accordingly, said intended use is not afforded any patentable weight for the purposes of this examination.

For the reasons stated above, the rejections under 35 U.S.C. 102 are sustained.

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Conclusion

31. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

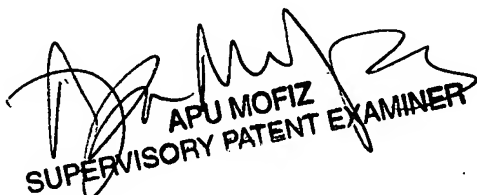
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Kim whose telephone number is (571) 272-2737. The examiner can normally be reached on M-F, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Apu Mofiz can be reached on (571) 272-4080. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER